PATIENT INFORMATION GUIDE

Facts about the SQUID™ Liquid Embolic Agent in the embolization of the Middle Meningeal Artery as an adjunct in the treatment of Chronic Subdural Hematoma

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SQUID LIQUID EMBOLIC AGENT PATIENT GUIDE

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1. Definition of Medical Terms

Anesthesia (general or local)
Anesthesia means the loss of sensations, such as pain, temperature or touch. General anesthesia means you will be given a drug or gas to make you unconscious during a procedure. Local anesthesia means the loss of sensation limited to a specific area of the body.

Angiography
Angiography is a procedure used to help diagnose and treat blood vessel disease. A special type of liquid that can be seen with x-ray machines is injected into the blood vessel. X-ray machines can then be used to see the blood vessels, diagnose disease, and aid the doctor during treatment of the disease.

Chronic Subdural Hematoma (cSDH)
A chronic subdural hematoma (cSDH) is a slow-growing collection of old blood that accumulates on the surface of the brain, under the skull. It typically develops weeks after a minor head injury, often one that may not be remembered. Small veins in your brain may stretch and tear, leaking blood that accumulates gradually and can press on the brain.

Computed Tomography (CT) scan
A CT scan is an advanced imaging technique that uses X-rays and computer processing to produce detailed cross-sectional images of the body.

Dimethyl Sulfoxide (DMSO)
DMSO is a liquid used during some procedures to help deliver medication safely through a catheter. Once it enters the body, DMSO is quickly broken down (metabolized) and eliminated through the kidneys and lungs. Some patients may notice a temporary garlic-like taste or odor on their breath or skin after the procedure, which is normal and goes away within a short time. The body clears DMSO naturally without long-term effects.

Hypersensitivity (allergies)
Hypersensitivity is a condition in which there is an exaggerated response by the body to a material or medication. The reaction is commonly referred to as an allergic reaction. The reaction can be very serious and may increase in severity with each successive exposure to the medication.

Liquid Embolic Agent (LEA)
A liquid embolic agent (LEA) is a fluid that is injected into a blood vessel where it hardens to intentionally and permanently block blood flow. In cSDH, embolization of the middle meningeal artery (MMA) works to cut off the blood supply feeding the hematoma, reducing inflammation and preventing recurrence of the hematoma. Your doctor can provide additional information on other embolization materials that are available to be used to block the middle meningeal artery if desired.

Magnetic Resonance Imaging (MRI) Scan

MRI scan uses a powerful magnetic field and radiofrequency pulses**,** to take high-detail images of soft tissues in the body**,** including the brain.

Microcatheter

A microcatheter is long, thin, tube-like device which is inserted through a small cut in the patient's leg or arm and guided through the blood vessel by the doctor. Once the microcatheter is positioned at the desired target location, it can be used to deliver various materials to treat or diagnose a disease. During a middle meningeal artery embolization procedure, a microcatheter is used to deliver the SQUID Liquid Embolic Agent to the middle meningeal artery in the brain.

Middle Meningeal Artery (MMA)

The middle meningeal artery (MMA) is a blood vessel that supplies blood to the protective lining around the brain. In some people, blood from this artery can contribute to bleeding around the brain, called subdural hematoma.

2. What is Chronic Subdural Hematoma (cSDH)?

A chronic subdural hematoma (cSDH) is a slow-growing collection of old blood that accumulates on the surface of the brain, under the skull. It typically develops weeks after a minor head injury, often one that may not be remembered. Small veins may stretch and tear, leaking blood that accumulates gradually and can press on the brain.

2.1 Common Symptoms

Symptoms may appear gradually and can include: headaches, trouble walking or feeling unsteady, confusion or memory changes, weakness on one side of the body, increased sleepiness, but it's important to note that not everyone has all these symptoms.

Chronic subdural hematoma is more common in older adults, people taking blood thinners, those who drink alcohol heavily, individuals with balance difficulties or frequent falls. Treatment depends on the size of the hematoma and your symptoms.

2.2 Treatment Options

1. Observation. Small hematomas without symptoms may be watched with follow-up scans.
2. Open Surgery. A small hole can be made in the skull to drain the blood and release the pressure.
3. Minimally Invasive Surgery. Through a small incision a doctor can use LEAs delivered to the MMA through a microcatheter to block tiny blood vessels feeding

the hematoma so it can shrink on its own. This also reduces the chance of the blood coming back. This embolization can be done alone or in addition to surgery.

3. Description of the SQUID™ Liquid Embolic Agent

SQUID is the trade name for a LEA manufactured by Balt USA. The SQUID is delivered through a microcatheter placed in the MMA. The SQUID begins to harden immediately when it comes into contact with bodily fluids, such as blood. Once hardened, SQUID stays in place to permanently block blood flow in the MMA with the goal of reducing the chance that the hematoma will come back.

4. When Should the SQUID™ Liquid Embolic Agent Not Be Used?

The use of SQUID is contraindicated when any of the following conditions exist:

- When optimal catheter placement is not possible
- When vasospasm (temporary narrowing of an artery) stops blood flow

5. Risks and Benefits

Benefits

MMA embolization with SQUID™ is expected to:

- Reduce or eliminate blood flow feeding the hematoma
- Reduce the likelihood of the hematoma coming back
- Reduce need for additional procedures after embolization

Potential Risks

Although uncommon, potential risks include:

- Problems at the insertion site (where the doctor inserts the catheter in your leg or wrist), such as pain, bruising, bleeding, swelling, infection, or damage to the blood vessel or nearby tissue
- Allergic reaction
- Blocked or narrowed blood vessels, which may reduce blood flow
- Heart problems, such as irregular heartbeat or heart attack
- Catheter-related problems, such as the catheter becoming stuck
- Stroke or reduced blood flow to the brain
- Death

- Risks related to X-ray exposure used during the procedure (skin irritation, burns, hair loss, eye problems such as cataracts, or delayed cancer risk)
- Headache
- Severe bleeding or blood vessel bursting
- Fluid buildup in the brain (hydrocephalus)
- Infection
- Inflammation (swelling or irritation)
- Nervous system problems such as weakness, numbness, trouble speaking
- Unintended blockage of nearby blood vessels, which may cause vision problems, facial numbness or pain, facial weakness, or hearing problems
- Problems affecting other organs
- Problems at the catheter insertion site (where the doctor enters the blood vessel)
- Kidney failure
- Breathing problems or lung failure
- Seizure
- Blood clot or reduced blood flow
- Blood vessel problems (narrowing, blockage, damage, spasm, or low blood pressure)
- Blood vessel spasm (temporary narrowing of a blood vessel)

Some risks may be unforeseeable and can vary based on individual health conditions. If you have questions about any potential risks, consult your physician.

6. What to Expect Before, During, and After the Procedure

6.1 Before the Procedure

Your doctor will evaluate you which may include:

- Medical and medication history
- Neurological and physical examination
- Blood tests
- Imaging (CT or MRI)
- Angiography (x-ray imaging of your brain and vessels leading up to your brain)

Your doctor may recommend that you take aspirin or other medications prior to the procedure, depending on your health condition. Your doctor may also recommend stopping some medications before the procedure.

6.2 During the Procedure

- Your doctor will give you medicine to sedate you with a mild sedative or, most commonly, with general anesthesia (general anesthesia is often preferred). The procedure will start with a small cut in the leg or arm to insert a thin tube (called a catheter). Using special X-ray guidance, the doctor gently moves the catheter to a blood vessel in the head called the MMA. Once the catheter is in place, SQUID is carefully injected through the catheter into the artery. The SQUID then hardens and stays in place to block blood flow into the hematoma. After this, the catheter is removed from your body. Imaging tests such as a CT scan or MRI will be used before or after the procedure to check the results.
- The embolization itself takes only minutes; however, preparation and catheter placement may take longer.
- Total procedure time is generally under one hour.

6.3 After the Procedure

You will be monitored in a recovery area in the hospital. Common experiences include:

- Groin or arm tenderness at the catheter insertion site
- Headache or nausea
- A temporary garlic-like smell due to DMSO metabolism (usually resolves within 24–48 hours)

Patients can typically leave the hospital within 4–6 hours if no surgery is required. Most individuals resume normal activities within 2–3 days. Occasionally, an overnight hospital stay may be needed.

7. Post Procedure Care

There are no SQUID™-specific care requirements. However, follow all medical instructions provided by your doctor. These may include:

- Temporary medication changes
- Activity restrictions
- Instructions for monitoring symptoms

Questions to Discuss with Your Physician:

- Are there activities I should avoid after the procedure?
- Are dietary changes required?
- What should I do if I experience new or worsening symptoms?

The Importance of Following Your Doctor's Instructions

Your physician will advise you if any steps will be required before or after the embolization procedure. It is important for your safety to carefully follow the directions and medications prescribed by your doctor.

STEM Clinical Trial

STEM study was a randomized controlled trial, which means that the study compared patients who received SQUID to those who did not. .Patients were randomly assigned to either the test group (treated with SQUID™) or the control group (not treated with SQUID™). The study was conducted at twenty-five (25) sites in the United States and seven (7) sites in Europe (France, Germany, and Spain). About half of the patients (144 patients) received SQUID™ MMA embolization in addition to surgery or medication changes, these patients were assigned as the test group. The other half of patients (166 patients) received surgery or medication changes without embolization, these patients were assigned as the control group. Out of a total of 310 patients who were randomly assigned to either the test or control group, 303 patients were evaluated for study results. The main study results were evaluated at 180 days and the patients continued to be followed for further evaluations out to one (1) year.

The results of this clinical trial showed that patients who received SQUID™ in addition to surgery or medication changes (test group) had a lower risk of needing additional procedures than those that were treated with surgery or medication changes alone (control group). Patients in the test and control groups had similar rates of major

disabling stroke or death within 180 days. These results showed that patients receiving SQUID™ in addition to surgery or medication changes experienced a benefit with minimal additional risk.

	SQUID + Surgery or Medication Changes (Test Group)	Surgery or Medication Changes Alone (Control Group)
Need for additional procedure	About 10 out of 100 (10.3%)	About 32 out of 100 (31.7%)
Death for any reason	About 8 out of 100 (8.3%)	About 5 out of 100 (5.4%)
Death from neurological reason	Less than 1 out of 100 (0.7%)	About 2 out of 100 (1.8%)
Major Disabling Stroke	About 1-2 out of 100 (1.4%)	About 1 out of 100 (1.2%)
New Seizure	About 9 out of 100 (9.0%)	About 3-4 out of 100 (3.6%)
Access site complications[1]	About 1-2 out of 100 (1.4%)	Not Applicable
Worsening cSDH	About 12 out of 100 (12.5%)	About 24 out of 100 (24.1%)

[1]Access site complications are injury in the leg or arm where the microcatheter entered the body

Note: The listed event rates are approximate, please see the device label for exact event rates

Additional Information

The following publication is available for additional information on the treatment of cSDH and SQUID Liquid Embolic Agent:

1. Fiorella D, Monteith SJ, Hanel R, et al; STEM Investigators. Embolization of the middle meningeal artery for chronic subdural hematoma. *N Engl J Med*. 2024. doi:10.1056/NEJMoa2409845

User Assistance Information

Refer to the instructions for use (IFU-052) for a complete list of potential complications, precautions or warnings.

Additional information may be requested from:

Balt USA
29 Parker
Irvine, CA 92618
Customer Service: 949-788-1443
e-mail: http://www.baltgroupcom

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